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BEFORE THE UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD

RESEARCH INTEGRITY ADJUDICATIONS PANEL

In the matter of:) Board Docket No. A-93-91
Robert C. Gallo, M.D.)
)

OFFER OF PROOF
OF THE
OFFICE OF RESEARCH INTEGRITY

COMES NOW the Office of Research Integrity ("ORI") and files this Offer of Proof in compliance with the Board's Preliminary Determination of Respondent's Motion (July 6, 1993) and Clarification of Panel's Order and Ruling on Request for Extension of Time (July 21, 1993). In support of its Offer of Proof,¹ ORI would respectfully show as follows:

I. INTRODUCTION

¹ In addition to the Offer submitted by ORI, the Witness and Exhibit Lists will be finalized with additional information concerning the areas noted by the Board, including designations as expert/fact witness, area(s) of testimony, and academic and other relevant credentials. Copies of supplemental exhibits will be provided with the revised exhibit list. Witnesses and exhibits listed in the Offer are identified to satisfy the purposes of the Offer rather than to preclude presentation of additional or different testimonial or documentary evidence at the hearing which may be necessary for logistical reasons.

In its Final Report on the allegations of scientific misconduct against Dr. Robert C. Gallo, the ORI concluded that Dr. Gallo committed scientific misconduct with respect to his following statement published in his article in Science:²

These findings suggest that HTLV-III and LAV may be different. However, it is possible that this is due to insufficient characterization of LAV because the virus has not been transmitted to a permanently growing cell line for true isolation and therefore has been difficult to grow in quantity.

ORI Report at 28, 52.

This finding of scientific misconduct was made by ORI after an extensive investigation, including the efforts of its predecessor the Office of Scientific Integrity ("OSI"), the NIH, the Richards Panel (a panel of ten preeminent extramural scientists/scholars nominated by the National Academy of Science and appointed by the Acting Director of the NIH), and an Expert Scientific Panel (three extramural experts appointed by the OSI and ORI to provide advice on the conduct of the investigation and evaluation of the evidence). See Exhibits H-184, H-185, H-186, H-188, H-199, H-200, H-224.

² "Detection, Isolation, and Continuous Production of Cytopathic Retroviruses (HTLV-III) from patients with AIDS and Pre-AIDS," Popovic, M; Sarngadharan, M.G.; Read E., and Gallo, R.C.: Science 224: 497-500 (May 4, 1984). This publication is referred as the "Popovic Paper" or the "Science paper."

In its Final Report, ORI also specifically identified four findings of inappropriate conduct Dr. Gallo which had provided the essential context for its evaluation of the allegations against Dr. Gallo.³ These are summarized below:

Allegation A1.⁴ In April - May 1983, Dr. Gallo inappropriately inserted changes into a paper written by scientists at the Pasteur Institute (the "Barré-Sinoussi paper.").⁵ The paper had been forwarded to Dr. Gallo for his assistance in having it accepted for publication by Science. Exhibit H-6. In the process of shepherding the paper, and eventually serving as its peer reviewer, Dr. Gallo both authored an Abstract and made significant substantive modifications which advanced his own hypotheses rather than those of the Pasteur scientists. Exhibits H-11 through H-13. These representations were not identified as comments by Dr. Gallo but rather added as gratuitous and self-serving changes purportedly representing the views and findings of the French authors. Exhibit H-13.

Allegation A2. Dr. Gallo was Senior Author on the Popovic paper. Exhibit H-81. ORI has found that Dr. Popovic committed scientific misconduct based on four groupings of nine separate

³ These allegations were raised publicly in an article in the Chicago Tribune by John Crewdson, "The Great AIDS Quest- A Special Report" (November 19, 1989) (Exhibit H-177).

⁴ These findings are identified with the number and letter assigned by the Board in its Preliminary Determination.

⁵ F. Barré-Sinoussi, et al., Science 220: 868 (May 20, 1983). (Exhibit H-13). This publication will be referred to as the "Barre-Sinoussi paper."

falsifications in that paper. However, the 3-1/2 page paper contains 13 additional erroneous statements, as well as the false statements concealing the use and significance of LAV (Allegation 8, infra) and the identity and origin of the cell line (Allegation A4, infra). Thus, the paper was replete with at least 22 incorrect statements concerning LTCB research, at least 11 of which were falsifications amounting to serious deviations from accepted standards for conducting and reporting research.

See also Allegation A3.

Allegation A3. Dr. Gallo was the Laboratory Chief at the Laboratory of Tumor Cell Biology during the relevant period. As Laboratory Chief, Dr. Gallo was responsible for ensuring the research in his laboratory was conducted and reported in a manner consistent with the applicable standards. The fulfillment of this responsibility included the institution and management of recordkeeping and data retrieval systems sufficient to support the methodologies and reports of research in the laboratory. His responsibilities also included supervision of laboratory activities concerning the appropriate use and release of reagents. See Allegation A4, infra. As Laboratory Chief, Dr. Gallo was responsible for ensuring the accuracy, integrity, and safety of the conduct of scientific research in the LTCB as well as the reporting of that research.

ORI found that Dr. Gallo's failure or refusal to meet his obligations as Laboratory Chief created an atmosphere which interfered with, rather than ensured, the accurate and

appropriate conduct and reporting of scientific research. See Allegations 8, A2, A4.

Allegation A4. ORI determined that Dr. Gallo failed to determine the source of "H9" in a timely manner and placed inappropriate restrictive conditions on access of other scientists to LTCB reagents. See also Allegations A2, A3 supra. Dr. Gallo knew or should have known that the cell line termed "H9" in the Popovic paper was merely a clone of a widely-known and readily available T-cell line, HUT-78. Dr. Gallo's obscuring the identity and origin of this cell line, especially when coupled with his selective and restrictive release of this and other reagents, constitutes a serious deviation from accepted standards for the conduct and reporting of scientific research.

ORI noted the perhaps singular importance of the research reported by LTCB scientists in their four Science papers in May 1984. The failures and deficiencies noted above have marred these advances because of the unacceptable circumstances of the research, the interwoven inaccuracies and falsifications in its manipulated reporting, and the monopolistic hoarding of its reported reagents. These activities have permanently clouded any legitimate discoveries made by the LTCB, inviting and culturing indefensible allegations ranging from fraud to misappropriation.

ORI determined that the preferable course of reporting its findings was to announce its finding of scientific misconduct that Dr. Gallo misrepresented the use and significance of LAV in the Popovic paper in light of the inseparable context of its four

other findings. Thus, in its Final Report, ORI not only explained its finding of scientific misconduct in Dr. Gallo's false reporting of the use and significance of LAV but also explained the context in which that finding was made and should be evaluated, i.e. the pattern of inappropriate conduct and scientific misconduct articulated in Allegations A1 through A4.

The inclusion of these four areas of deficiencies is particularly important in light of the recommended sanctions of placing the ORI Report in Dr. Gallo's personnel file and supervision for a period of three years. The Report should be as complete as possible both to relay the appropriate information to the limited number of officials with access to the personnel file and to inform those charged with the laboratory supervision of the appropriate areas for special scrutiny during the period of supervision.

The Board, however, has now ordered ORI to parse its findings to identify which of these areas of censurable conduct, either separately or in the aggregate, constitute scientific misconduct and, for each instance of scientific misconduct, to identify sufficient documentary and testimonial evidence to support a finding of scientific misconduct. In response to this directive, ORI submits this Offer of Proof.

II. ALLEGATIONS OF SCIENTIFIC MISCONDUCT

ORI alleges the following findings of scientific misconduct:

A. Allegations A1, A2, A3, A4 and 8, in the aggregate, constitute scientific misconduct. These allegations, taken together, constitute a pattern of conduct showing intent to deceive and misrepresent the results of scientific research so as to constitute a serious deviation from commonly accepted practices in the community, i.e. scientific misconduct.⁶

B. Allegation 8, alone, constitutes scientific misconduct. The facts underlying allegations A1-A4 will be used to prove Allegation A8. These facts demonstrate a pattern of conduct showing an intent to deceive and misrepresent the results of scientific research and are relevant and material to the proof of Allegation 8. These underlying facts will be used to prove Allegation 8.

C. Allegation A4, alone, constitutes scientific misconduct. The facts underlying Allegations A1-A3 and 8 will be used to prove Allegation 8. These facts demonstrate a pattern of conduct showing an intent to deceive and misrepresent the results of scientific research and are relevant and material to Allegation A4.

⁶ In the alternative, ORI alleges that any combination of allegation 8 and one or more of the other allegations constitutes, in the aggregate, scientific misconduct. In addition to the documents and witnesses identified below in support of each allegation, ORI intends to call, *inter alia*, Drs. Schaffer, Hadley, McGinnis, Bivens, Woolf, Huth, Richards, Morgan, Goldberger, Rall, and Raub to testify that one or more deviations of commonly accepted practices may be combined to constitute a finding of misconduct.

III. DISCUSSION OF ALLEGATIONS AND SUPPORTING EVIDENCE

In the Offer which follows, ORI has, for the purpose of most clearly and comprehensively advising Dr. Gallo and the Board of the allegations in this appeal, articulated in detail by allegation, rather than by aggregate groupings of allegations, the appropriate standards and factual evidence. Where the aggregation of allegations alters the appropriate standard(s), by synergy or otherwise, the amended standard is noted.

A. Allegation A1 - The Barré-Sinoussi Paper

In its Final Report, ORI found that:

Dr. Gallo's role in the Barré-Sinoussi paper: ORI found that Dr. Gallo's actions were 'gratuitous, self-serving, and improper.'... ORI believes that Dr. Gallo's actions reflect Dr. Gallo's propensity to misrepresent and mislead in favor of his own research findings or hypotheses.

ORI Final Report at 53.

1. Summary of The Offer of Proof

ORI will present evidence that Dr. Gallo's actions with respect to the Barré-Sinoussi paper were, by a preponderance of the evidence, violative of accepted practices within the scientific community in 1983. First, ORI will demonstrate that Dr. Gallo abused his authority as a peer reviewer by pressuring Dr. Montagnier either to accept Dr. Gallo's substantive changes or suffer the derailment of the publication.

Second, ORI will demonstrate that the substantive changes made by Dr. Gallo were "gratuitous and self-serving." These

changes subverted the emphasis of the paper intended by its authors and promoted Dr. Gallo's own hypothesis.

Third, ORI will demonstrate that Dr. Gallo further obfuscated the work of the French authors to his own advantage by knowingly crafting an Abstract for the paper which misstated its findings and observations.

Overall, ORI will demonstrate that Dr. Gallo's acts show an intent to subvert the work of the Pasteur scientists and are part of a pattern of conduct by Dr. Gallo that "repeatedly misrepresents, suppresses and distorts data and their interpretation in such a way as to enhance his own claims to priority and primacy." Report of Richards Panel, Exhibits H-224, 226.

2. The Applicable Standards For Peer Review In 1983

In 1983, as now, peer reviewers of manuscripts submitted for publication in scientific journals were expected to provide an objective and unbiased evaluation of the manuscript for scientific merit and for the importance of the work, either from a public health or basic research perspective. This fundamental purpose of peer review required that the reviewer divorce any personal theories and beliefs about the research topic and apply a yardstick based primarily on the adequacy of the methodology, the significance of the findings, and the scientific and/or public health importance of the reported research.

In 1983, as now, it was violative of accepted practices for peer review for a reviewer to make actual edits or changes in a

manuscript or to prepare entire portions of a manuscript, such as an Abstract. In the highly unusual circumstance where such contributions by a reviewer were needed, these changes must have been explicitly approved by the author(s) of the manuscript.

In 1983, as now, peer reviewers were not expected to communicate directly with the author(s) of a manuscript, or to use their position of influence to coerce the author(s) to make or accept changes in the manuscript. Reviewers were expected to suggest, even as a condition of publication, certain changes in a manuscript, but such suggestions or changes were invariably made to the editor of the journal in question.

3. Dr. Gallo's Inappropriate Conduct As Reviewer of the Barré-Sinoussi Paper

On April 15, 1983, Dr. Luc Montagnier of the Pasteur Institute sent a draft manuscript [the "Pasteur paper" or the "Barré-Sinoussi paper"] to Dr. Gallo for his review. Exhibits H-6, H-11, H-12, H-13. Dr. Montagnier was senior author on this paper. The paper reported the isolation and detection of LAV, a retrovirus which the French identified as a possible etiological agent of AIDS. Dr. Gallo had offered to use his influence to ensure that the paper would be published in Science. Dr. Gallo secured the commitment of Science to include the Barré-Sinoussi paper with three other papers pending publication. These other papers reported possible links between the HTLV-I virus, a virus discovered in 1982 by researchers in Dr. Gallo's lab, and AIDS. Two of these other papers were written by Dr. Gallo and his

associates; the third paper was written by a long-time collaborator of Dr. Gallo, Dr. Max Essex. See, e.g., Science 220: 865-67 (May 20, 1983), Exhibit H-15. Dr. Gallo read the Pasteur paper and, on April 19, 1983, forwarded it, along with his comments, to Ruth Kulstad, an editor at Science. Exhibit H-7. See also Exhibits H-8, H-9, 178, 182.

Dr. Gallo introduced several improper and self-serving changes in the Barré-Sinoussi paper. ORI will show that Dr. Gallo altered the paper to reflect his own theories about the cause of AIDS. Specifically, ORI will show that Dr. Gallo inappropriately added a sentence: "The virus [LAV] appears to be a member of the human T-cell leukemia virus (HTLV) family." Exhibit H-13 at 868. Similarly, he altered another sentence in the manuscript to read: "We tentatively conclude that this virus, as well as all previous HTLV isolates, belong to a family of T-Lymphotropic retroviruses that are horizontally transmitted in humans...." Id. Dr Gallo's insertion of these references to "HTLV," coupled with his definition of HTLV as "Human T-Cell Leukemia Virus," rather than "Human T-Cell Lymphotropic Virus," deliberately and erroneously linked LAV and HTLV-I.⁷ The Pasteur scientists had made no such conclusion or suggested any such link and, in fact, no such link exists. Moreover, Dr. Montagnier has denied seeing any reference to HTLV-I in the draft of the paper

⁷ Dr. Gallo's definition of HTLV as the "leukemia" virus equates to a definition of HTLV as HTLV-I, i.e., the virus discovered by the Gallo lab in 1982.

he saw prior to publication. Exhibits H-207; H-189, Attachment 1. Indeed, Dr. Montagnier stressed the dissimilarities between HTLV-I and LAV, his new virus, in telephone conversations with Dr. Gallo. Id. See also Testimony of Dr. J.C. Chermann (co-author).

Through his changes, Dr. Gallo was able to subvert the article to appear to be a confirmation of his personal misplaced theory that the AIDS virus was linked to his own HTLV-I virus. Dr. Gallo clearly succeeded in perverting the theories the French authors were trying to convey, a perversion that would appear to the scientific community as an independent confirmation of Dr. Gallo's theory that AIDS was a disease related to his HTLV-I virus.⁸ The evidence will further demonstrate that, when Dr. Gallo forwarded the paper to Science with his comments, he clearly downplayed the significance of the changes by disingenuously representing them to the journal editor as "mainly stylistic and grammatical. ... The minor changes have been discussed with the senior author (Dr. Montagnier) and he agrees with all." Exhibits H-7, H-189, H-206, H-207, H-213.⁹

⁸ Dr. Gallo also inserted a discussion of his HTLV-II virus into the paper.

⁹ Years later Dr. Gallo disparagingly attributed his own changes to the Pasteur scientists. For example, in a November 1986 patent litigation declaration, Dr. Gallo stated that, "The Pasteur group reported a major cross reaction of HTLV-III and HTLV-I." Exhibit H-169.

- In an April 30, 1986 history of key events, Dr. Gallo stated: "It is important to note that on that 1983 paper the Pasteur group report a significant cross reaction with HTLV-I. Later they conclude that it was a mistake."

- In a September 1985 memorandum to Dr. Fischinger, Dr. Gallo quoted from the language he inserted into the Barré-

ORI will further show that the Abstract written by Dr. Gallo to accompany the Pasteur paper continued the subversion of the paper begun in his alteration of the paper's text. ORI will demonstrate that the Abstract was a highly significant part of the paper, designed to summarize the findings and conclusion of the authors in a concise manner for the scientific community. In fact, a literature search of scientific papers prompts disclosure of the Abstract only. However, the Abstract penned by Dr. Gallo significantly misrepresented the original content of the paper by again connecting the Pasteur virus to Dr. Gallo's own HTLV virus, a connection never intended by the Pasteur authors.

Specifically, the Gallo Abstract asserts that "[a]ntibodies from serum of this patient [BRU] react with proteins from viruses of the HTLV-I subgroup," and that the Pasteur virus "has an internal antigen (25) similar to HTLV p24." Exhibit H-13 (emphasis supplied) However, the original text of the Pasteur paper had actually reported that the BRU serum "contains antibodies that recognize a common antigen present on HTLV-I producing cells" Exhibit H-11 at 2 (emphasis supplied); i.e. the antigen was very plausibly of cellular, not viral, origin. See also Exhibit 12 at 2 ("... serum of the patient reacted strongly with surface antigen(s) present on HTLV infected cells.") (emphasis supplied).

Sinoussi paper and states that: "Remember, at this stage [March 1983 to fall of 1983] the Pasteur group had one claim of one virus and they reported it was significantly cross reactive with HTLV-I...." Exhibit H-149A; See also H-98.

Additionally, the Pasteur authors had clearly stated that "the RUB retrovirus [from BRU] contains a major P25 protein, similar in size to that of HTLV, but immunologically different from the latter." Exhibit H-1 at 6. See also Exhibit H-12 at 6. There was no mention in the Gallo Abstract of this vital difference.

Thus, ORI will demonstrate that Dr. Gallo's claim in the Abstract that BRU serum reacted with HTLV-I viral proteins is not substantiated by the paper. Indeed, it is a subversion of the Pasteur paper, deliberately penned by Dr. Gallo to promote his own theories and an LTCB virus.

Moreover, the evidence demonstrates that the Abstract was not written in concert with the French authors. Rather, Dr. Gallo gratuitously penned the self-serving Abstract to foster his own aims and accomplishments, even over Dr. Montagnier's and Dr. Chermann's protestations. Exhibit H-189; Testimony of Dr. J.C. Chermann. Dr. Gallo's intent in manipulating the paper will be further evidenced by several other instances in 1983 where Dr. Gallo continued to alter and denigrate the work described in the Pasteur paper by attempting to connect that work to the HTLV family, despite the objections of Dr. Montagnier. See, e.g., Exhibit H-189, Attachment 1; Exhibit H-21 at 8; Exhibit H-23; Exhibit H-24; see also Exhibit H-213. Cf. n 9, supra.

4. Dr. Gallo Violated the Standards for Peer Review

ORI will prove that Dr. Gallo's abuses of the peer review process by altering the paper and writing the Abstract to foster

his own theories and purposes, in a manner inconsistent with the findings and beliefs of the authors of the paper, constitute a serious deviation from standards accepted in the scientific community in 1983. ORI will demonstrate that Dr. Gallo abused his authority as a reviewer of this article by bullying his inappropriate, self-serving, changes past the authors of the paper under the implied threat of delaying or outright canceling publication of the paper. Exhibit H-207. ORI will further show Dr. Gallo's manipulative efforts by demonstrating that, when he communicated his changes to the Science editor, Dr. Gallo deliberately underplayed the significance of his changes and additions, denominating them as "stylistic and grammatical" or "minor" as well as grossly overstating the authors' agreement to the changes. Exhibit H-7. Dr. Gallo was able to accomplish this by, in part, inappropriately taking total control over review of the paper, serving both as mystery co-author and sole peer reviewer in contravention of accepted peer review policies.¹⁰ ORI will show that the fundamental underpinning of the peer review process rests in the objectivity of the reviewer. Unfortunately, Dr. Gallo's actions demonstrate a total absence of objectivity and a conflict of interest, resulting in an undermining of the peer review process. ORI will prove that any

¹⁰ Although the names of Dr. Popovic and Dr. Sarin, both in the LTCB, are included in the letter to Science as reviewers, only Dr. Gallo signed the review letter. Furthermore, these two individuals reported directly to Dr. Gallo and could not be considered independent reviewers.

review by the publication's editors and the Pasteur authors does not alter the fact that Dr. Gallo acted outside the standards which were and are accepted in the scientific community for the peer review of articles.¹¹

5. ORI's Witnesses

ORI will present testimony from the following witnesses to establish the accepted standards for peer review, the significance and inappropriateness of the changes made to the paper, the significance and inappropriateness of the content of the Abstract, the inappropriateness of the manner in which Dr. Gallo undertook his peer review responsibilities and the inappropriateness of the manner in which the peer review process was carried out in this case: Drs. Judith Areen; Robert Goldberger; Edward Huth; Arnold Levin; Howard E. Morgan; Mary Jane Osborn; Frederic Richards; Joseph Sambrook; Priscilla Schaffer; John D. Stobo; Robert F. Wagner; Patricia Woolf; Luc Montagnier; Francoise Barré-Sinoussi; Jean-Claude Chermann; Donald Francis; Malcolm Martin; and Suzanne Hadley. The testimony of these witnesses, in conjunction with the documentary evidence, will prove that Dr. Gallo's acts violated the standard of conduct in 1983 for peer review of the Pasteur article and, as part of a pattern of conduct showing intent to mislead and

¹¹ ORI will demonstrate that, while the method by which this paper was reviewed and published may be viewed as an indictment of Science, Dr. Gallo's culpability remains clear. As a peer reviewer, a scientist is under an obligation to ensure there are no conflicts of interest present in reviewing another's work.

deceive, constituted scientific misconduct. This standard precluded the reviewer from making changes to the reviewer's own work over that of the authors' where the changes misstate the research of the authors. This is true even where the paper is subject to further review by the publication's editors and its original authors.

B. Allegation A2: Dr. Gallo Failed to Fulfill His Obligations as a Senior Author on the Popovic Paper¹²

In its Final Report, ORI found that:

In light of his role as senior author of the Popovic paper, Dr. Gallo must bear substantial responsibility for the numerous discrepancies in the Popovic paper, including the four instances of scientific misconduct attributed to Dr. Popovic. The scientific and public health importance of the research undertaken in the LTCB imposed an obligation for accuracy in reporting the methodologies and results of this groundbreaking research - an obligation that Dr. Gallo failed to meet.

ORI Final Report at 53.

1. Summary of the Offer of Proof

ORI will offer proof that Dr. Gallo seriously deviated from accepted standards of scientific practice by his failure to fulfill his responsibilities as senior author on the Popovic paper.¹³ Exhibit H-81. See also Allegations A3, A4 and 8. Dr.

¹² ORI incorporates by reference its Post Hearing Memorandum In Support of a Finding of Scientific Misconduct and the Proposed Actions Against Dr. Mikulas Popovic, (August 27, 1993), as well as its Offer of Proof, Case No. 93-100.

¹³ ORI's present exhibits include some of Dr. Gallo's written responses to questions posed by OSI regarding the 16 allegations initially raised regarding the Science paper. See Exhibits H-190 through H-194. ORI will supplement its exhibit

Gallo's acts are part of a pattern of conduct that "repeatedly misrepresents, suppresses and distorts data and their interpretation in such a way as to enhance his own claims to priority and primacy." Exhibit H-224. "Response to the Charge to the Consultant to the Director of the National Institutes of Health Concerning the Investigation of Drs. Gallo and Popovic" (January 29-30, 1992) (the "Richards Panel Report"), Exhibit 24 at 1.

During 1983-84, Dr. Gallo was the Laboratory Chief of the Laboratory for Tumor Cell Biology ("LTCB"), which was within the National Cancer Institute at the National Institutes of Health ("NIH"). Testimony of Dr. Gallo at the Popovic hearing; Exhibit H-237. As Chief of this Laboratory, Dr. Gallo is responsible for supervising and evaluating the conduct of the scientists working at the LTCB. Testimony of Dr. William Raub; Dr. Malcolm Martin; Dr. Howard Morgan; Dr. Priscilla Schaffer; Dr. Kenneth Berns; Suzanne Dahlman (Commissioned Corps Personnel); Dr. Popovic; Dr. Suzanne Hadley. Dr. Gallo recruited Dr. Popovic to work at the LTCB in 1980. Among other things, Dr. Popovic was responsible for growing retroviruses in cell lines. Prior to May 1984, Dr. Gallo had published approximately 34 scientific papers with Dr. Popovic. Testimony of Dr. Gallo at the Popovic hearing; Exhibit H-237.

list with the additional responses of Dr. Gallo made to OSI on July 25, 1990. See n. 1, supra.

By 1983, Dr. Gallo was aware of Dr. Popovic's work habits and ability to draft scientific papers. Testimony of Dr. Gallo at the Popovic hearing. Dr. Gallo told Dr. Popovic to accelerate the completion of the Science paper because Dr. Popovic had a tendency to procrastinate the drafting of scientific papers. It was Dr. Gallo's judgment that Dr. Popovic had sufficient time to finish the Science paper. Id.

Dr. Popovic was the primary author on the Science paper. Id. Dr. Gallo was the senior author on the Science paper. Id.; Exhibit H-81. Drs. Gallo and Popovic edited and re-drafted the Science paper. Exhibits H-48 through H-56, H-191 through H-194, H-201, H-208, H-216, H-218; Testimony of Drs. Gallo and Popovic and Ruth Kulstadt at the Popovic hearing.

ORI will show that the paper at issue contains numerous demonstrably false and incorrect statements, and that Dr. Gallo breached his responsibility as senior author by introducing them or by failing to correct them.

2. Standards for Authorship in Scientific Publications

All authors on a published scientific paper are generally responsible for its content. However, all scientists would agree that the senior author and the first author are more responsible than the other authors for ensuring the accuracy and completeness of the paper. In fulfilling this obligation, the senior author has a special responsibility for ensuring the authenticity and accuracy of all data reported in the paper.

The senior author is responsible for ensuring a true and faithful representation of all methods and procedures reported in the paper. This duty includes responsibility for both acts of omission as well as acts of commission. The senior author is responsible both for ensuring that steps in the experimental methodology are not omitted from a paper (intentionally or negligently) and for ensuring that steps or results that were not performed are not reported as part of the methodology.

Under this duty, the scientist is responsible for false statements which are, or should be, known to be false. The failure of Dr. Gallo to fulfill this obligation of senior authorship is a serious deviation of commonly accepted principles in the scientific community.

A reasonable researcher in Dr. Gallo's position in 1983 and 1984 would have considered the conduct which is described below to be a serious deviation from commonly accepted practices within both the scientific community as a whole and NIH in 1983-1984 for proposing, conducting, or reporting research.

A scientist must report experimental results accurately because this reporting affects the ability of other scientists to evaluate the results as well as the quality and rigor of the reported work. Scientists must report all research honestly and accurately so that it can be replicated. Scientists build their concepts and theories with individual bricks of scientifically-ascertained facts. The research process can proceed with

confidence only if scientists can assume that the previously reported facts on which their work is based are correct. If the bricks are in fact false, jeopardizing the public health and safety, then the scientific wall of truth may crumble, as well as the public fisc. Such actions threaten the very integrity of the scientific process. Thus, all scientists share a commitment to provide observations honestly obtained, recorded, and published.

In addition, the senior author has a duty to report data and methodology accurately so that the reader can independently assess the validity of the experimental method, attempt to repeat the experiment to test the accuracy of the results, and evaluate the overall significance or conclusions of the reported experiments. Thus, Dr. Gallo is responsible for those false statements in the Science paper that could mislead the reader about the rigor or replicability of the actual methodology or could prevent the reader from independently evaluating the quality of the experiments.

When the reported research deals with a pandemic, such as AIDS, the senior author has a higher duty to be accurate because more professional attention will be given to the scientific paper. For example, if a paper contains the description of the methodology for propagating the AIDS virus in a permanent cell line, but the description leaves out certain steps in the methodology, then other scientists may not be able to build upon the reported discovery.

The NIH provides federal research funds to scientists as an incentive to find and report scientific truth, benefitting the nation by the joint effort of groups of scientists, rather than the persuasiveness of a single scientist. In 1984, the LTCB received over \$10 million in federal research funds, not including non-appropriated funds. In this regard, the standards applicable to scientists in the LTB, and its Laboratory Chief, are even higher than those required of other scientists.

In sum, the senior author must share responsibility with the first author for including false information or delivering key information, that could affect the incentive or ability of other scientists to evaluate and/or replicate the reported experiment(s). Exhibits H-253-56; H-258; H-262; H-263-272; H-274; H-275; H-277-80; H-294.

3. The Science Paper Contains Numerous Falsifications

The Science paper contains at least the following falsifications of data presented in the Popovic hearing:

- a. The sentence on page 498 that "concentrated fluids were first shown to contain particle associated RT" is false in two respects. First, the concentrated fluids of individuals were not all positive for particle associated reverse transcriptase ("RT") activity. Second, the concentrated fluids were not "first shown" to be positive for "RT" activity. See Exhibits H-47 through H-57; H-67; H-68; H-69; H-81; H-145; H-190

through H-194; H-201; H-216; H-218; H-323; H-324, H-330 through H-336. (Allegation 7 in the ORI Report).

b. Table 1 contains four entries listed as "ND" for immunofluorescent assays ("IFA") at the six-day time period. The legend defines "ND" to mean "not done." The laboratory notebook of Dr. Popovic's laboratory technician Elizabeth Read-Connole establishes that these experiments were performed and the results were positive for one entry and negative for the remaining three entries. The evidence will show that Dr. Popovic changed the data listed in the notebook to "ND" because the data were contrary to his expectations and suppositions about the results. Instead of reporting the actual test results, Dr. Popovic said the experiment was not performed. Because each listing of "ND" is a false statement, Dr. Gallo is responsible for four separate acts of falsification in Table 1.

Exhibits H-67 through H-69; H-190 through H-194; H-201; H-216; H-218; H-323; H-324; H-330 through H-336. (Allegation 10 in the ORI Report).

c. Table 1 also contains an entry for "10%" positive. The laboratory notebook of Elizabeth Read-Connole shows a corresponding entry of "very few cells [,] positive for rabbit antibody." The evidence will demonstrate there is no scientific basis for the use of this "10%" figure. Thus, the listing of "10%" is a falsification

of the laboratory data. See Exhibits H-190 through H-194; H-67 through H-69; H-201; H-216; H-218; H-227; H-323; H-324; H-330 through H-336. (Allegation 11 in the ORI Report).

d. Table 2 contains two entries as "ND" for the IFA and electron microscopy ("EM") tests of the sample from patient SN. The laboratory data demonstrate that the experiments for these entries were in fact performed and were negative. The evidence will show that data listed in the notebook were reported as "ND" because the data were contrary to Dr. Popovic's expectations and suppositions about the results. Instead of reporting the actual test results, the authors reported that the experiments were not performed. Because each listing of "ND" is a false statement, Dr. Gallo is responsible for two separate acts of falsification in Table 2. See Exhibits H-37; H-47; H-67; H-68; H-69; H-190 through H-194; H-161; H-166. (Allegation 14 in the ORI Report).

In sum, the testimonial and documentary evidence will demonstrate that Dr. Gallo is responsible as senior author for at least nine separate acts of falsification which were at issue in the Popovic hearing (i.e., two for the "first shown" sentence; four for the "ND" entries in Table 1; one for the "10%" entry in Table 1; and two for the "ND" entries in Table 2). Dr. Gallo's failure to correct these false statements is a material breach of

his obligation as senior author and Laboratory Chief of the LTCB to ensure the accurate and honest reporting of research. See also Allegation A3, infra.

The finding for this allegation is not derived wholly from the allegations at issue in the Popovic hearing. Thus, even if the Board were to find that Dr. Popovic were not guilty of scientific misconduct with respect to the allegations listed above, Dr. Gallo is nevertheless independently responsible for these falsifications because of his position as senior author of the Science paper and his position as the Laboratory Chief of the LTCB. Indeed, the Board's decision in Popovic may well establish Dr. Gallo's culpability regardless of its disposition of the specific allegations against Dr. Popovic.

In addition to the false statements at issue in the Popovic hearing, the Science paper contains 13 other incorrect and misleading statements. As senior author and Laboratory Chief of the LTCB, Dr. Gallo is responsible for these false statements.¹⁴

- a. The Science paper provided no specification of when and how often fresh cells were added to the HT (H4) cultures depicted in Figure 2a and described in the methods section. (Allegation 1 of the ORI Report).

Dr. Popovic has acknowledged that "Figure 2a was, 'not

¹⁴ Most of these falsifications were specifically and separately raised as allegations by OSI or ORI during their investigations. References are to OSI or ORI allegations.

accurate' and 'not precise' because it does not have arrows indicating re-feeding." Exhibit H-218 at 27.

b. The Science paper provided no specification of the number of fresh cells added to the HT (H4) cultures depicted in Figure 2a and described in the methods section. (Allegation 1 in the ORI Report). The authors' failure to state the number of fresh cells added to the cultures is a material falsification because the AIDS virus can kill all the cells in the culture if it is underfed. Exhibit H-81 at 499.

c. The Science paper provided no specification of why and how often new or additional patient samples were added to the HT (H4) cultures depicted in Figure 2a. (Allegation 1 in the ORI Report). The authors failed to explain to the reader that additional patient samples were added to the cultures on November 15, 1983 and January 2, 1984. Exhibits H-147; H-201. New patient samples were added to avoid loss of the culture. Nevertheless, the authors failed to inform the reader about these additions or the reasons for the additions. Exhibit H-319 at 83-85. The authors' failure to inform the reader of material information regarding the additions of these patient samples conceals and misrepresents the actual methodology.

d. The Science paper provided an insufficient description of the ten patient samples allegedly used to create the